





















The Clorox Company

October 15, 2013

Mr. Demson Fuller, Product Manager 32 U.S. Environmental Protection Agency Document Processing Desk (REGFEE) Office of Pesticide Programs -7504P One Potomac Yard 2777 S. Crystal Drive Arlington, VA 22202



Re: New Product Application for Clorox® HL, EPA Reg. No. 11346-to be assigned OPP EE0163

Dear Mr. Fuller:

The Clorox Company is submitting a new product application for Clorox® HL which is essentially a repack registration based on Boris, EPA Reg. No. 67619-26. Most of the Clorox® HL label was copied from that registration, which was reviewed and accepted August 14, 2013; among the few things that were changed on this label are the basic name and the EPA registrant number. We also deleted some organisms and deleted some institutional/commercial uses because we plan to sell this product in the "home healthcare" market.

We would normally file this submission as a "repack" registration except that we are submitting an efficacy study to support this registration as well as Clorox® HW, a new registration packet that will be submitted in the next few days. Normally we would not need a data matrix but because we are submitting the efficacy data, we are submitting a certification with respect to citation of data, and two data matrices (both EPA and public). We list all studies including the new efficacy data we are submitting.

The following volumes are enclosed – Volume I (administrative materials – one copy) and 3 copies of Volumes II, an efficacy volume of supplemental information in support of *Clostridium difficile*.

Volume I contains the following:

- Form 8570-1, Application for Pesticide Registration (OPP EE0163) (+ 2 copies)
- PRIA pre-payment copy of pay.gov statement
- Certification with Respect to Label Integrity
- Diskette containing e-label with the filename: 011346-xxxxx.20131015.RC027010.pdf
- Proposed labeling 1 label + 4 copies (label # RC027010)
- Child Resistant Packaging Certification (2 copies)
- Form 8570-27, Formulator's Exemption Statement
- Form 8570-4, Confidential Statement of Formula (Basic); 1 original 2 copies
- Form 8570-34, Certification with Respect to Citation of Data
- Form 8570-35, Data Matrix (Agency Internal Use Copy)
- Form 8570-35, Data Matrix (Public File Copy)

Clorox® HL, EPA Reg. No. 11346-to be assigned October 15, 2013

We enclose an extra copy of both the cover letter and the transmittal document for the submitted study.

We request a copy of the efficacy Data Evaluation Record (DER) to be included with the Agency's response to this letter.

We believe that the following pesticide registration service fee information applies:

o Category: A540

o Fee amount: \$4,863.00 o Decision time: 5 months

Thank you for your help in the timely review of this application. If you have any questions, please call me at (925) 368-9017 or J. Evelyn Lawson at (925) 368-9026.

Sincerely,

Elisa Estremera

Federal Registration Specialist

Clorox Professional Products Company

CTCPSERC@Clorox.com

TRANSMITTAL DOCUMENT

1. Name and address of submitter

The Clorox Company c/o PS&RC P.O. Box 493 Pleasanton, CA 94566-0803 Attention: Elisa Estremera

2. Regulatory action in support of which this package is submitted

Clorox® HL, EPA Reg. No. 11346-to be assigned Efficacy study with public literature articles

These data also support Clorox® HW, EPA Reg. No. 11346-to be assigned, being submitted to EPA a few days after this registration is submitted

3. Transmittal date

October 15, 2013

4. Vol. I Administrative Materials

- A) Cover letter
- B) Form 8570-1, Application for Pesticide Registration (OPP EE0163) + 2 copies
- C) Pay.gov pre-payment receipt
- D) Proposed labeling 1 label + 4 copies (label # RC027010)
- E) Diskette containing e-label with the file name 011346-xxxxx.20131015.RC027010.pdf

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MRID assigned:

Signature

- F) Child Resistant Packaging Certification (original + 2 copies)
- G) Form 8570-27, Formulator's Exemption Statement
- H) Form 8570-4, Confidential Statement of Formula (Basic); 1 original + 2 copies
- I) Form 8570-34, Certification with Respect to Citation of Data
- J) Form 8570-35, Data Matrix (Agency Internal Use Copy)
- K) Form 8570-35, Data Matrix (Public file copy)

5. Submitted study

Vol. II. Supplemental Information in Support of Clostridium difficile Efficacy Claims

lostridium difficile Efficacy Claims

Company Official:

Elisa Estremera

Federal Registration Specialist

Company Name:

The Clorox Company

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